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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/326,020	06/04/99	PORTER	J CELL-0072

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EXAMINER

ROBINSON, B

ART UNIT

PAPER NUMBER

1625

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DATE MAILED: 04/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/326,020

Applicant(s)

PORTER ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 5-11, 13 and 16-19 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 15, 21, 20 20) ☐ Other: ____

Detailed Action

The examiner notes the applicant's election of group II for prosecution with traverse. The applicant traverses the election/restriction requirement on the alleged basis that the mere fact that certain phenylalanine derivatives may inhibit beta amyloid protein production or protease, does not mean that these derivatives have different modes of operation, functions, or effects in the disclosed invention.

1. However, the examiner notes that in the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, while providing enablement for Alk1 equal to -CH₂-, -CH(CH₃)-, -

C(CH₃)₂-, -(CH₂)₂- on page 8 of the specification, R₄ equal the various groups listed at lines 34-36, page 12 of the specification, and lines 1-15, page 13, and Alk₂ equal to -CH₂- as specified in line 16, page 14, of the specification, does not reasonably provide enablement for Alk₁ equal to all optionally substituted aliphatic or heteroaliphatic chains, R₄ equal to all optionally substituted aliphatic, cycloaliphatic or polycycloaliphatic groups, and Alk₂ equal to all alkylene groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

3. Claim 14 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for R₁ equal to all possible cycloaliphatic, polycycloaliphatic, polyheterocycloaliphatic, aromatic, or heteroaromatic groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance

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for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

4. Claim 15 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of the various unrelated diseases listed. There is also no known cure in the art for multiple sclerosis. The specification does not enable any person skilled in the art to which it *keep* pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

5. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

6. Claims 1 and 14 in part are objected to as being drawn to an improper Markush group on the grounds of lack of a common nucleus. The improper Markush group *keep* objection finds antecedent basis in case law. Compare *In re Swensen* 156 USPQ 180; *In re Ruzicka* 66 USPQ 226; *In re Winnek* 73 USPQ 225; *In re Harnish* 206 USPQ 300, 305 (CCPA 1980).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 and 14 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

keep A. In claim 1 in part, the terms "substituted aliphatic" and "heteroaliphatic chain" in line 7, page 2 of claim 1, and the phrase "~~optionally-substituted-aliphatic, cycloaliphatic, or polycycloaliphatic group~~" in line 16 of page 2 of claim 1 are indefinite. The scope of the terms are so broad that they are virtually meaningless.

B. In claim 14 in part, the terms "~~cycloaliphatic, aromatic or heteroaromatic~~" in line 17 of claim 14 and the phrase "~~cycloaliphatic, polycycloaliphatic, polyheterocycloaliphatic, aromatic, or heteroaromatic~~" in lines 23-24, claim 13 are indefinite. The scope of the terms are so broad that they are virtually meaningless.

8. The closest prior art reference is Tauchi et. al. (See Reference N). The difference between the Tauchi compound and the instantly claimed compound is the X1-R4 moiety. In the instant compound, the X1-R4 moiety is -N(R3)CO-aliphatic group. In the Tauchi compound, the X1-R4 moiety is hydrogen. At pages 1-13, see the compound, Benzeneacetic acid, 4-(3-pyridinylmethyl)-,hydrochloride.

The prior art reference does not teach nor suggest to one of ordinary skill in the art how to modify the prior art compound to derive the instant compound.

9. The IDS filed 11/22/99, 8/28/00, 2/26/01, and 3/23/01 have been considered. The references that have been crossed out will not be considered until they are provided to the examiner.

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10. Claims 5, 6, 7, 8, 9, 10, 11, 13, and 16-19 are objected to because they are based on a rejected claim.
11. Claim 12 in part appears to be allowable.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5337. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-223.



April 11, 2001



ALAN L. ROTMAN
PRIMARY EXAMINER